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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JANSSEN PRODUCTS, L.P., et al.,

Plaintiffs,

v.

LUPIN LIMITED, et al.,

Defendants.

OPINION

Civ. No. 10-5954 (WHW)

Walls, Senior District Judge

This matter comes before the Court on remand from the Court of Appeals for the Federal Circuit in response this Court's Fed. R. Civ. P. 62.1(b) indicative ruling that it would modify its final judgment order and trial opinion entered on August 14, 2014 to reflect the terms of a settlement between Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC and Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. Decided without oral argument under Fed. R. Civ. P. 78, the Court grants the parties' joint motion to modify the order.

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, "Janssen") and G.D. Searle, LLC brought this action against Defendants Lupin Limited and Lupin Pharmaceuticals Inc. (collectively, "Lupin"), Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan"), and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva"). Plaintiffs, patent-holders and drug-makers, sued Defendants, generic drug manufacturers, for alleged infringements of patents on the chemical compound darunavir,

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used in the manufacture of Plaintiffs' product, Prezista, arising out of Defendants' filing of Abbreviated New Drug Applications ("ANDAs") seeking approval to sell generic versions of Prezista. Amended Complaint, ECF No. 267 ¶ 1. The facts of the case are presented thoroughly in the Court's August 14, 2014 opinion finding patent infringement by the Defendants and granting Plaintiffs' request for a permanent injunction barring Defendants from manufacturing, importing, using or selling their ANDA products in the United States, ECF No. 943, and are incorporated here by reference.

In the opinion and accompanying order, ECF No. 944, the Court held in part that the sale of darunavir tablets described in Mylan's ANDA 202136 would infringe claim 13 of U.S. Patent No. 7,772,411 (the '411 Patent), which is held by Plaintiffs, *id.* at 2, and enjoined Mylan from "using, selling, or offering for sale in the United States, or importing into the United States, the [ANDA 202136 product] or any darunavir product made by any colorable variation of the process used to make Mylan's ANDA 202136 product." *Id.*

Defendants Mylan and Lupin filed a motion to amend the August 14, 2014 injunctive order on August 19, 2014, ECF No. 947, which the Court denied on October 7, 2014. ECF No. 2012. Defendants Mylan and Lupin separately appealed the August 14, 2014 judgment "and all underlying adverse opinions, orders, decisions, and rulings subsumed within said Judgment and/or made prior to entry of Judgment in this action, and/or relating to the scope of any relief award pursuant to said Judgment" on September 12, 2014. Lupin Notice of Appeal, ECF No. 983 at 2; Mylan Notice of Appeal, ECF No. 984 at 2. The appeals are currently pending before the Federal Circuit. *Janssen Products, L.P. v. Lupin Limited*, No. 14-1842 (Fed. Cir. 2014) ("*Lupin*"); *Janssen Products, L.P. v. Mylan Pharmaceuticals, Inc.*, No. 14-1843 (Fed. Cir. 2014) ("*Mylan*") (deconsolidated Dec. 30, 2015 (see *Mylan*, No. 14-1843, ECF No. 13)).

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On November 9, 2015, after Janssen and Mylan completed briefing but before the Federal Circuit heard oral argument on Mylan's appeal, Janssen and Mylan executed a settlement agreement and license agreement resolving Janssen's claims regarding the '411 Patent. Joint Mot. Indicative Ruling, ECF No. 1063 at 1. Under the agreement, Janssen will permit Mylan to manufacture and sell ANDA products at a specified date before the expiration of the '411 patent. *Id.* at 3. The August 14, 2014 injunctive order currently bars Mylan from manufacturing or selling these products before the expiration of the patent. *Id.*

At the parties' request, the Federal Circuit granted a stay of further appellate proceedings pending the completion of the settlement. *Id.* at 2; *Lupin*, No. 14-1842, ECF No. 84. On November 20, 2015, Janssen and Mylan filed a motion in this Court under Fed. R. Civ. P. 62.1 for an indicative ruling that, if the case were remanded, the Court would modify the August 14, 2014 injunctive order to allow Mylan to manufacture and sell ANDA products during the term of the '411 patent as permitted in the settlement agreement. ECF No. 1063. The Court granted the parties' joint motion on December 11, 2015 and issued an indicative ruling. ECF No. 1065. In the opinion, the Court discussed why a Rule 60(b) order modifying the judgment would be appropriate in this case. The Court's findings and analysis are incorporated here.

On December 14, 2015, the parties filed a joint motion requesting that the Federal Circuit dismiss Mylan's appeal with prejudice and remand the matter to this Court for modification of the August 14, 2014 injunctive order consistent with the indicative ruling. *Lupin*, 14-1842, ECF No. 85. On January 21, 2016, the Federal Circuit granted the motion to remand, directing this Court to "consider modification of the final judgment order consistent with the district court's indicative ruling" and to "apply the principles enunciated in *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 29 (1994)." *Mylan*, 14-1843, ECF No. 16.

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On remand, the Court now considers whether to modify the order consistent with its indicative ruling.

STANDARD OF REVIEW

In *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, the Supreme Court held that the “mere fact” of “mootness by reason of settlement does not justify vacatur of a judgment under review.” 513 U.S. 18, 29 (1994). Whether vacatur of the judgment is justified is an “equitable” determination, and “exceptional circumstances may conceivably counsel in favor of such a course.” *Id.* “Of course, even in the absence of, or before considering the existence of, extraordinary circumstances, a court of appeals presented with a request for vacatur of a district-court judgment may remand the case with instructions that the district court consider the request, which it may do pursuant to Federal Rule of Civil Procedure 60(b).” *Id.*

Fed. R. Civ. P. 60(b) allows a court to provide relief from a judgment or order when, among other things, “applying the judgment order prospectively is no longer equitable” (subsection (b)(5)), or “for any other reason that justifies relief” (subsection (b)(6)). The Court’s power to grant relief under this rule is narrow. “Due to the overriding interest in the finality and repose of judgments, a Rule 60(b) motion is considered extraordinary relief which should be granted only where extraordinary justifying circumstances are present.” *Katz v. Twp. of Westfall*, 287 Fed. Appx. 985, 988 (3d Cir. 2008) (quotations and citations omitted).

“[I]t is appropriate to grant a Rule 60(b)(5) motion when the party seeking relief from an injunction or consent decree can show a ‘significant change either in factual conditions or in law.’” *Agostini v. Felton*, 521 U.S. 203, 215 (1997) (quoting *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 384 (1992)). If the movant can demonstrate this significant change in factual

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conditions or law, the Court should “consider whether the proposed modification is suitably tailored to the changed circumstances.” *Rufo*, 502 U.S. at 383.

DISCUSSION

The parties seek a limited modification of the Court’s August 14, 2014 order enjoining Mylan from manufacturing and selling ANDA products. The proposed order does not modify the Court’s earlier findings of fact or conclusions of law, ECF No. 943, nor does it modify the Court’s judgment against Defendants Lupin and Teva. Proposed Order Modifying Judgment, ECF No. 1063-2 Ex. A. Instead of holding that Mylan’s production of the darunavir tablets described in ANDA 202136 would infringe claim 13 of the ‘411 patent and enjoining Mylan from producing, using, selling, or importing the tablets at any time before the ‘411 patent’s expiration, the proposed modified order states that production would infringe the ‘411 patent “absent a license from Plaintiffs” and enjoins Mylan from producing the tablets “before such date provided under the Settlement Agreement and License Agreement between Mylan and Plaintiffs.” *Id.* at 1-2.

As discussed in the Court’s indicative ruling, ECF No. 1065 at 5-7, modification of the August 14, 2014 injunctive order is appropriate under Rule 60(b)(5) and 60(b)(6) because applying the judgment prospectively “is no longer equitable.” Fed. R. Civ. P. 60(b)(5). There has been a “significant change . . . in factual conditions,” *Agostini v. Felton*, 521 U.S. at 215, namely that Janssen and Mylan have settled and that Janssen has agreed to allow Mylan to sell darunavir tablets at a certain future date. Given the Third Circuit’s strong policy “in favor of voluntarily settlement agreements,” *Ehrheart v. Verizon Wireless*, 609 F.3d 590, 594 (3d Cir. 2010), it would be inequitable for the Court to refuse to modify a judgment preventing the parties from carrying out this settlement. The proposed modified order is appropriate here because it is

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“suitably tailored to the changed circumstances.” *Rufo*, 502 U.S. at 383. The proposed order leaves intact the Court’s findings of fact and law and the injunctive relief ordered against the remaining Defendants. Additionally, Mylan would still be liable for patent infringement if it produced or sold darunavir tablets before the date specified in the settlement agreement or otherwise in violation of the “license from Plaintiffs.” ECF No. 1063-2 Ex. A at 1-2. The modified judgment does not “discard” the Court previous decision, *Vertex*, 648 F. Supp. 2d at 239, but simply allows the settling parties to comply with the terms of their settlement agreement.

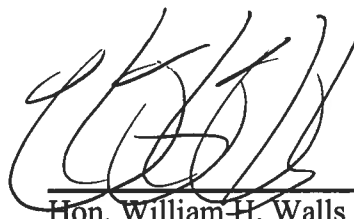
Modification of the trial order on remand from the Federal Circuit under Rule 60(b) is consistent with the principles enunciated in *U.S. Bancorp Mortgage Co.* 513 U.S. at 29, so the Court will grant the parties’ joint motion.

CONCLUSION

The Court finds that the jointly requested Rule 60(b) relief is warranted, ECF No. 1063, and that modification of the trial order on remand from the Federal Circuit under Rule 60(b) is consistent with the principles enunciated in *U.S. Bancorp Mortgage Co.* 513 U.S. at 29. The Court issues the proposed order modifying judgment with respect to Mylan, ECF No. 1063-2 Ex. A, allowing the settling parties to comply with the terms of their settlement agreement. An appropriate order follows.

DATE:

15 March 2016

A handwritten signature in black ink, appearing to read 'William H. Walls', written over a horizontal line.

Hon. William H. Walls
United States Senior District Judge